UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALAN PINTO,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA GMBH, and NOVARTIS AG,

Defendants.

Civil Action No.: 08-CIV-6672

Document electronically filed

DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S ANSWER

Defendant Novartis Pharmaceuticals Corporation ("NPC") responds to Plaintiff's Complaint ("Complaint") as follows:

BACKGROUND

1. NPC denies any and all wrongful conduct as alleged. NPC further denies that Plaintiff suffered any damage or harm as a proximate result of any alleged wrongful conduct by NPC in paragraph 1.

2. NPC denies each and every allegation contained in paragraph 2.

JURISDICTION AND VENUE

3. NPC admits, based on information and belief, that the amount in controversy exceeds $75,000 and that subject matter jurisdiction exists in the Southern District of New York.

4. Paragraph 4 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it conducts business in New York.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 5.

PARTIES

6. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 6.

7. NPC admits that it is and has been at all relevant times a corporation incorporated under the laws of the State of Delaware with its principal place of business in the State of New Jersey.

8. NPC denies that it is a subsidiary or alter-ego of Novartis Pharma GmbH. The remaining allegations in paragraph 8 relate to parties other than NPC and assert legal conclusions to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 8.

9. Paragraph 9 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 9.

10. NPC denies that it is a subsidiary or alter-ego of Novartis AG. The remaining allegations in paragraph 10 relate to parties other than NPC and assert legal conclusions to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 10.

11. Paragraph 11 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. NPC admits that Novartis AG indirectly owns a 100% interest in NPC and that Novartis AG owns the patent on pimecrolimus and the trademark

for the word "Elidel" in the United States. NPC denies the remaining allegations in paragraph 11.

12. Paragraph 12 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 12.

13. NPC admits that the plaintiff uses the term "Novartis Defendants" collectively to refer to several defendants. NPC denies any legal relationship arising from the collective reference. By way of further answer, NPC is a separate corporation and should be referred to individually to maintain clarity in the pleadings. NPC is answering the Complaint solely on its own behalf and is not acting in any capacity for any other defendant.

14. Paragraph 14 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 14 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 14.

15. Paragraph 15 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 15.

FACTUAL BACKGROUND

16. NPC admits that United States Patent number 5,912,238 is for pimecrolimus and is owned by Novartis AG. The remaining allegations in paragraph 16 are directed toward other defendants and NPC lacks sufficient knowledge or information to form a belief as to the truth of those allegations, which are therefore denied.

17. NPC admits that pimecrolimus is a macrolide lactone and can be derived from ascomycin, and that it was developed under the name SDZ ASM 981. NPC denies the remaining allegations in paragraph 17.

18. NPC admits that pimecrolimus and tacrolimus bind to the macrophilin-12 receptor, but with different affinities. Pimecrolimus and tacrolimus can be calcineurin inhibitors because the drug macrophilin complex can block the calcium-induced phosphatase action of calcineurin. Blocking the action of calcineurin prevents the release of inflammatory cytokines from T cells and also inhibits proliferation of activated T cells. NPC denies the remaining allegations in paragraph 18.

19. NPC admits that the United States Adopted Names Council has assigned the names of "pimecrolimus" and "tacrolimus." The remaining allegations in paragraph 19 concern the intent and mental impressions of parties other than NPC to which no response is required. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 19, which are therefore denied.

20. Paragraph 20 contains allegations regarding other parties to which no response is required. To the extent the allegations relate to NPC, NPC admits that the FDA approved pimecrolimus as safe and effective for the following indication on December 13, 2001, as set forth in the package insert which was approved by the FDA on that date and provides:

> Elidel (pimecrolimus) Cream 1% is indicated for short-term and intermittent long-term therapy in the treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative conventional therapies. (See **DOSAGE AND ADMINISTRATION** Section)

To the extent that any further response is required, NPC denies the allegations in paragraph 20.

21. Denied. Eczema is a common name for atopic dermatitis.

22. NPC admits that at least one calcineurin inhibitor was approved as indicated by the FDA to prevent organ rejection in transplant patients prior to December 13, 2001. NPC denies the remaining allegations in paragraph 22.

23. NPC denies the allegations in paragraph 23. By way of further answer, FDA approved pimecrolimus as safe and effective on December 13, 2001.

24. NPC denies the allegations in paragraph 24. By way of further answer, FDA approved pimecrolimus as safe and effective on December 13, 2001, subject to the following commitment (among others):

> We agree to conduct a registry study of pediatric patients (aged 2-17, with emphasis on the younger ages) with atopic dermatitis followed through adulthood for those who have long-term intermittent treatment with Elidel (pimecrolimus) 1% Cream to assess the risk of developing systemic malignancies.

25. NPC admits that on October 30, 2003, a meeting open to the public of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee was held to discuss how to approach long-term monitoring for cancer occurrence among patients treated for atopic dermatitis with pimecrolimus and tacrolimus. NPC denies the remaining allegations in paragraph 25.

26. NPC denies the allegations in paragraph 26.

27. NPC admits that the "Summary Minutes" for the October 30, 2003, subcommittee meeting stated in part: "For children under 2, because of immune system development issues and lack of understanding regarding the development of other systems in the very young a Box warning was recommended." NPC further admits that the FDA did not choose to change the

package insert to include a black box warning. To the extent any further response is required, NPC denies the remaining allegations in paragraph 27.

28. NPC admits that anecdotal reports of malignancies in patients using pimecrolimus were reported to the FDA after October 2003. NPC denies that such reports were caused by pimecrolimus. NPC denies the remaining allegations in paragraph 28.

29. NPC admits that pimecrolimus was discussed at a meeting of the Pediatric Advisory Committee on February 15, 2005. NPC denies the remaining allegations in paragraph 29.

30. Paragraph 30 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, NPC admits that on March 10, 2005, the FDA issued a Public Health Advisory "about a potential cancer risk from use of Elidel® (pimecrolimus) and Protopic® (tacrolimus)" in which it stated that "FDA will require labeling changes for Elidel and Protopic, including the placement of a boxed warning about the potential cancer risk." NPC denies the remaining allegations in paragraph 30.

31. Paragraph 31 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, NPC admits that FDA and NPC agreed to appropriate language for the black box warning in January 2006, and that this change was then made to the label.

THE NOVARTIS DEFENDANTS

32. Paragraph 32 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® for the approved indications listed on the label for Elidel®.

33. Paragraph 33 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it received approval from the FDA on December 13, 2001 to market Elidel® for certain approved indications and that the terms of the FDA's approval, set forth in writing in their approval letter, speak for themselves. NPC denies the remaining allegations in paragraph 33.

34. Paragraph 34 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and markets Elidel® for certain approved indications. NPC denies the remaining allegations in paragraph 34.

35. Paragraph 35 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and markets Elidel® for certain approved indications. NPC denies the remaining allegations in paragraph 35.

36. Paragraph 36 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits the allegations as they relate to NPC only.

37. NPC denies the allegations in paragraph 37.

38. Paragraph 38 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and markets Elidel® for certain approved indications using ordinary marketing practices. NPC denies the remaining allegations in paragraph 38.

39. Paragraph 39 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that the number of

prescriptions for Elidel® through 2005 totaled in the millions. NPC denies the remaining allegations contained in paragraph 39.

40. Elidel® was approved as safe and effective by the FDA on December 13, 2001 and has been sold and continues to be sold with FDA-approved package inserts and labels. NPC denies any allegation inconsistent with the specific terms of the package inserts or labels and denies all remaining allegations in paragraph 40.

41. Elidel® was approved as safe and effective by the FDA on December 13, 2001 and has been sold and continues to be sold with FDA-approved product labeling. NPC denies any allegation inconsistent with the specific terms of the product labeling and denies all remaining allegations in paragraph 41.

42. Paragraph 42 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, the allegations in paragraph 42 are denied.

43. Paragraph 43 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, the allegations in paragraph 43 are denied.

44. Paragraph 44 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 44 are denied.

45. Paragraph 45 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, the allegations in paragraph 45 are denied.

46. Paragraph 46 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 46 are denied.

47. Paragraph 47 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 47 are denied.

48. Paragraph 48 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 48 are denied.

49. Paragraph 49 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 49 are denied.

50. Paragraph 50 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 50 are denied.

51. Paragraph 51 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 51 are denied.

52. Paragraph 52 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 52 are denied.

53. Paragraph 53 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 53 are denied.

54. Paragraph 54 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 54 are denied.

FACTUAL ALLEGATIONS – ALAN PINTO'S CASE

55. Paragraph 55 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or his treating physician reviewed prior to October 2003 and denies the remaining allegations in paragraph 55.

56. Paragraph 56 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or his treating physician reviewed and denies the remaining allegations in paragraph 56.

57. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 57. To the extent that a response is required, NPC denies the allegations in paragraph 57.

58. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations that the plaintiff was diagnosed with a form of cancer, more specifically

Non-Hodgkin's Lymphoma, in August 2005. NPC denies the remaining allegations in paragraph 58.

59. NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or his treating physician reviewed and denies the remaining allegations in paragraph 59.

COUNT I
Products Liability Act – Failure to Warn

60. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

61. Paragraph 61 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 61 are denied.

62. Paragraph 62 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 62 are denied.

63. Paragraph 63 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 63 are denied.

64. Paragraph 64 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 64 are denied.

65. Paragraph 65 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 65 are denied.

66. Paragraph 66 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 66 are denied.

67. Paragraph 67 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 67 are denied.

68. Paragraph 68 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 68 are denied.

COUNT II
Strict Products Liability – Defective Design

69. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

70. Paragraph 70 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® for the approved indications listed on the label for Elidel®. NPC denies the remaining allegations in paragraph 70.

71. NPC denies the allegations in paragraph 71.

72. NPC denies the allegations in paragraph 72.

73. Paragraph 73 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 73.

74. Paragraph 74 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is

without sufficient knowledge or information to form a belief regarding how Plaintiff used Elidel®. NPC denies the remaining allegations in paragraph 74.

75. Paragraph 75 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 75.

76. Paragraph 76 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 76.

77. Paragraph 77 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 77.

78. Paragraph 78 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 78 are denied.

COUNT III
Breach of Express Warranty

79. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

80. Paragraph 80 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 80 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 80.

81. Paragraph 81 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 81 are denied.

82. Paragraph 82 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 82 are denied.

83. NPC denies the allegations in paragraph 83.

84. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 84.

85. NPC denies the allegations in paragraph 85.

86. Paragraph 86 contains legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 86 are denied.

87. Paragraph 87 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 87 are denied.

88. Paragraph 88 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 88 are denied.

COUNT IV
Breach of Implied Warranty

89. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

90. NPC denies the allegations contained in paragraph 90.

91. NPC denies the allegations contained in paragraph 91.

92. Paragraph 92 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, NPC is without sufficient knowledge or information to form a belief regarding how the plaintiff used Elidel®. To the extent that a response is required, NPC denies the allegations in paragraph 92.

93. NPC denies the allegations contained in paragraph 93.

94. Paragraph 94 contains legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 94 are denied.

95. Paragraph 95 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 95 are denied.

96. Paragraph 96 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 96.

COUNT V
Negligence

97. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

98. Paragraph 98 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® for the approved indications listed on the label for Elidel®. NPC denies the remaining allegations in paragraph 98.

99. Paragraph 99 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 99.

100. Paragraph 100 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 100.

101. Paragraph 101 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 101.

102. Paragraph 102 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 102.

103. Paragraph 103 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 103.

COUNT VI
Violation of New York G.B.L. § 349

104. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

105. Paragraph 105 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 105 are denied.

106. Paragraph 106 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 106 are denied.

107. Paragraph 107 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 107 are denied.

108. Paragraph 108 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 108 are denied.

109. Paragraph 109 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 109 are denied.

110. Paragraph 110 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 110 are denied.

RELIEF REQUESTED

NPC denies that plaintiff is entitled to any of the relief requested in subparts A-G or in any other WHEREFORE clause contained in the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim or cause of action against NPC upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar Plaintiff's claims against NPC in whole or in part.

THIRD AFFIRMATIVE DEFENSE

The doctrine(s) contained in Restatement (Third) of Torts, Product Liability § 6, bar Plaintiff's claims against NPC in whole or in part.

FOURTH AFFIRMATIVE DEFENSE

Applicable statutes of limitation bar Plaintiff's claims in whole or in part.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's misuse, abnormal use, or use without a prescription of the product or failure to follow instructions bars Plaintiff's claims in whole or in part.

SIXTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, then Plaintiff's claims are barred, in whole or in part, because he assumed the risks disclosed by the product label and instructions, by the prescribing physicians, or by other persons or entities.

SEVENTH AFFIRMATIVE DEFENSE

Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent he did not use Elidel®.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, his claim is barred to the extent he used the product without a prescription.

TENTH AFFIRMATIVE DEFENSE

The learned intermediary doctrine bars Plaintiff's claims.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the product at issue, Elidel®, was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or part, because the product at issue, Elidel®, complied with all applicable government safety standards and was not defectively or unreasonably dangerous.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing and supply of pharmaceutical products including Elidel®.

FOURTEENTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, then Plaintiff's claims are barred, in whole or in part, because Plaintiff suffered no compensable injury as a result of such use.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff and/or independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical conditions.

SIXTEENTH AFFIRMATIVE DEFENSE

If Plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor

responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiff's injuries or damages.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by Elidel®, which is denied, were the result of his own idiosyncratic reactions.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff failed to mitigate, which limits Plaintiff's damages and his claim is barred or, alternatively, any recovery should be reduced by the failure to mitigate.

NINETEENTH AFFIRMATIVE DEFENSE

NPC has no legal relationship or privity with Plaintiff and owes no duty to Plaintiff by which liability could be attributed to it.

TWENTIETH AFFIRMATIVE DEFENSE

NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which NPC specifically denies, then Plaintiff failed to give notice of any breach thereof.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are barred because such an award would violate NPC's due process, equal protection and other rights under the United States Constitution, the New York Constitution, and/or other applicable laws or constitutions.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are barred because Plaintiff has failed to allege conduct warranting imposition of punitive damages under New York and/or other applicable state laws.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred, in whole or in part, by Plaintiff's own contributory/comparative negligence.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff has received from collateral sources.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Elidel®.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claim for punitive damages is preempted, in whole or in part, by applicable federal law.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff is limited in the amount, if any, he may recover for punitive damages under New York law.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff is barred from recovering punitive damages because Elidel® was subject to pre-market approval by the FDA, was approved by the FDA, and/or was generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

THIRTIETH AFFIRMATIVE DEFENSE

Punitive damages against NPC cannot be recovered based on alleged fraudulent representations to the FDA. *See Buckman Co.* v. *Plaintiffs' Legal Comm.,* 531 U.S. 341, 343 (2001).

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims for fraud, misrepresentation, or a breach of trust are barred by Plaintiff's failure to plead them with particularity as required by Federal Rule of Civil Procedure 9(b) and/or New York C.P.L.R. 3016(b).

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims under G.B.L. § 349 are barred in their entirety because Elidel® was approved by the FDA, and NPC's conduct with regard to Elidel® was subject to and complied with FDA rules and regulations, including but not limited to FDA warning requirements, as well as statutes administered by the FDA. *See* G.B.L. § 349(d); *Morelli v. Weider Nutrition Group, Inc.*, 712 N.Y.S.2d 551, 552 (App. Div. 2000).

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims under G.B.L. § 349 are preempted because they conflict with federal law. *See Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239, 247-52 (3d Cir. 2007).

THIRTY-FOURTH AFFIRMATIVE DEFENSE

NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this Answer and its Affirmative Defenses.

WHEREFORE, Defendant Novartis Pharmaceuticals Corporation demands judgment dismissing Plaintiff's Complaint, together with costs and further relief as this Court deems just and proper.

Dated: July 25, 2008

Respectfully submitted,

/s/ Diane E. Lifton
Diane E. Lifton (DL-9673)
GIBBONS PC
One Pennsylvania Plaza, 37th Floor
New York, NY 10119-3701
Telephone: 212-613-2000
Fax: 212-290-2018

Of Counsel
SPRIGGS & HOLLINGSWORTH
1350 I Street, N.W.
Washington, DC 20005
Telephone: 202-898-5800
Fax: 202-682-1639

Attorneys for Novartis Pharmaceuticals Corporation